

**PATENT**  
**Serial No.: 08/471,474**  
**Attorney Docket No. 02356-0011-06**

claimed invention at the time the application was filed. The Examiner maintains that the specification only describes isolation of a single novel HIV-1 isolate, and fails to provide any evidence suggesting that additional HIV-1 isolates were isolated and purified. The Examiner alleges that the skilled artisan would conclude that Applicants were not in possession of any variants other than HIV-1<sub>MAL</sub>. Applicants traverse the rejection.

Applicants have previously pointed out the various portions of the specification that show that they were in possession of both HIV-1<sub>MAL</sub> and HIV-1<sub>ELI</sub>. The Examiner seems to have ignored this evidence that Applicants were in possession of both variants, as well as a broader class of evolutionarily-related variants. Instead of addressing the disclosure that Applicants pointed out in the last Amendment, the Examiner focuses on the sections of the specification that indicate that HIV-1<sub>MAL</sub> is the most preferred embodiment of the invention. Merely because more of the specification is directed to HIV-1<sub>MAL</sub> than HIV-1<sub>ELI</sub> does not mean, as the Examiner seems to indicate, that the specification does not contain written description support for claims to HIV-1<sub>ELI</sub>.

The law states that "[i]f a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met." *In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996). Thus, merely because the specification does not

provide every nuance about the HIV-1<sub>ELI</sub> strain does not mean that the claims are not supported by written description.

In an effort to show that the specification does support claims to HIV-1<sub>ELI</sub>, Applicants present the declaration of Denise Guétard, an independent expert in this field. This declaration states that the specification does support claims to HIV-1<sub>MAL</sub> and HIV-1<sub>ELI</sub>, as well as a broader genus of viruses, and that a skilled artisan would have understood that the Applicants had possession of the invention as of the earliest filing date of this application. (Guétard Declaration, ¶ 7-8).

The specification describes the isolation of characterization of HIV-1 isolates HIV-1<sub>MAL</sub> and HIV-1<sub>ELI</sub>. (Specification at 7, lines 10-24). The HIV-1<sub>ELI</sub> strain was isolated in 1983 from a 24-year old woman with AIDS from Zaire, while the HIV-1<sub>MAL</sub> strain was isolated in 1985 from a 7-year old boy from Zaire. Identification of a source for these two strains shows that they are distinct and that the inventors were in possession of both of them. (Guétard Declaration, ¶ 4).

Additionally, in Figures 3A-3F, Applicants describe the amino acid sequences of the Gag, Pol, Vif, Vpr, Env, and Nef proteins of HIV-1<sub>MAL</sub> and HIV-1<sub>ELI</sub> in comparison to HIV-1<sub>BRU</sub> and HIV-1<sub>ARV-2</sub>. This demonstrates that the inventors had isolated and sequenced these important viral proteins in HIV-1<sub>MAL</sub> and HIV-1<sub>ELI</sub>. (Guétard Declaration, ¶ 5). Respectfully, Applicants could not have determined the amino acid

sequences of the viral proteins for a virus they were not in possession of. Such an assertion is not logical.

In Fig. 4A, Applicants show that both HIV-1<sub>MAL</sub> and HIV-1<sub>ELI</sub> differ at the amino acid sequence level from HIV-1<sub>III<sub>B</sub></sub>, HIV-1<sub>BRU</sub>, and HIV-1<sub>ARV-2</sub> greater than 3.4 % in the entire Gag protein, 3.1% in the entire Pol protein, and 13.0% in the entire Env protein. Applicants had isolated, determined amino acid sequences for, and compared HIV-1<sub>MAL</sub> and HIV-1<sub>ELI</sub> to other known viruses. Additionally, it shows, in the bottom portion, that HIV-1<sub>ELI</sub> differs substantially from HIV-1<sub>MAL</sub>, preventing any arguments that strains are identical, or that only one was isolated. (Guétard Declaration, ¶ 6).

In the opinion of Mrs. Guétard, the description of the properties of both the HIV-1<sub>MAL</sub> and HIV-1<sub>ELI</sub> shows that the inventors had possession of both of these viruses. (Guétard Declaration, ¶ 7).

Furthermore, Applicants' description clearly conveys that Applicants had possession of the claimed genus of HIV-1 variants, in addition to HIV-1<sub>MAL</sub> and HIV-1<sub>ELI</sub>. In Figs. 3A, 3C, and 3E, the specific amino acid differences between Gag, Pol, and Env proteins of each of the isolates HIV-1<sub>MAL</sub>, HIV-1<sub>ELI</sub>, HIV-1<sub>BRU</sub>, and HIV-1<sub>ARV-2</sub> are shown. Using this information, Applicants described variable and conserved regions of HIV-1 Gag, Pol, and Env. (Specification at 10-17). Applicants' comparison of viruses

indicated that these viruses are evolutionarily related as diverging from a common origin. (Specification at 17, lines 17-33; Guétard Declaration, ¶ 9).

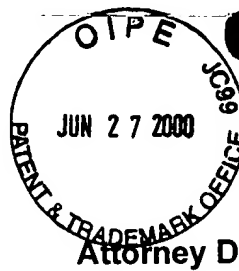
Thus, Applicants' described not only HIV-1<sub>MAL</sub> and HIV-1<sub>ELI</sub>, but also a group of HIV-1 viruses, which is of greater evolutionary divergence than the group consisting of HIV-1<sub>IIIB</sub>, HIV-1<sub>BRU</sub>, and HIV-1<sub>ARV-2</sub>. This group of viruses would contain not only HIV-1<sub>MAL</sub> and HIV-1<sub>ELI</sub>, but also variants of these viruses. (See Specification at 3, lines 4-5; Guétard Declaration, ¶ 10).

According to Mrs. Guétard, the skilled artisan would recognize that additional members of this group could contain amino acids sequences of HIV-1<sub>MAL</sub>, HIV-1<sub>ELI</sub>, or combinations of the two sequences. (Guétard Declaration, ¶ 11).

The Examiner cannot ignore the factual evidence presented in the specification showing that the inventors were in possession of both strains and the claimed HIV-1 genus of the invention. Therefore, Applicants' description would reasonably convey to the skilled artisan that Applicants had possession of the claimed invention. Accordingly, Applicants respectfully request withdrawal of the rejection.

### **Rejection Under 35 U.S.C. § 102(b) and 103**

Claims 23-25 were rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Meyers et al., 1990. The Examiner contends that, since Applicants have allegedly not provided an adequate



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written description of the invention, priority has not been extended under 35 U.S.C. §§ 119 or 120. The Examiner contends that, therefore, Meyers et al., 1990, is prior art and that isolate Z2Z6 appears to meet all the claim limitations. Applicants traverse the rejection.

Applicants claim priority to U.S. Application Ser. No. 07/038,330 filed April 13, 1987, and to French application 86401380.0 filed June 23, 1986. As discussed above, Applicants specification fulfills the written description requirement of 35 U.S.C. § 112, first paragraph. Accordingly, Meyers et al., 1990, cannot be considered "prior art", and Applicants respectfully request withdrawal of the rejection.

Applicants respectfully submit that this application is in condition for allowance and request the issuance of a Notice of Allowance. If the Examiner should disagree, he is invited to contact the undersigned to discuss any remaining issues.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully Submitted,

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